(2)

No. 04-607

Supreme Court, U.S.
FILED
DEC 14 2004
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS (doing business as LabCorp),

Petitioner,

v.

METABOLITE LABORATORIES, INC. and COMPETITIVE TECHNOLOGIES, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONER

JOHN P. HIGGINS
ALSTON & BIRD, LLP
Bank of America Plaza
101 South Tryon Street
Suite 4000
Charlotte, NC 28280
(704) 444-1000

JONATHAN S. FRANKLIN*
CATHERINE E. STETSON
JESSICA L. ELLSWORTH
HOGAN & HARTSON L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5766

* Counsel of Record

Counsel for Petitioner

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

TABLE OF AUTHORITIES

	Page
CASES:	
Duke Univ. v. *Madey*, 538 U,S. 959 (2003)	8
Funk Bros. Seed Co. v. *Kalo Inoculant Co.*, 333 U.S. 127 (1948)	6
General Elec. Co. v. *Wabash Appliance Corp.*, 304 U.S. 364 (1938)	5
Hewlett-Packard Co. v. *Bausch & Lomb Inc.*, 909 F.2d 1464 (Fed. Cir. 1990)	3, 4
Honeywell Int'l, Inc. v. *Hamilton Sundstrand Corp.*, 125 S. Ct. 458 (2004)	8
Insituform Tech. Inc. v. *CAT Contracting, Inc.*, 385 F.3d 1360 (Fed. Cir. 2004)	4
Manville Sales Corp. v. *Paramount Sys., Inc.*, 917 F.2d 544 (Fed. Cir. 1990)	1, 3, 4
McFarling v. *Monsanto Co.*, 125 S. Ct. 348 (2004)	8
Mentor H/S, Inc. v. *Medical Device Alliance, Inc.*, 244 F.3d 1365 (Fed. Cir. 2001)	4
Merck KGaA v. *Integra Lifesciences I, Ltd.*, 125 S. Ct. 237 (2004)	8
Micrel, Inc. v. *Linear Tech. Corp.*, 537 U.S. 946 (2002)	8
Minnesota Mining & Mfg. Co. v. *Chemque, Inc.*, 303 F.3d 1294 (Fed. Cir. 2002)	3, 4
Monsanto Co. v. *Bayer CropScience S.A.*, 537 U.S. 1027 (2002)	8
Warner-Lambert Co. v. *Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003)	3

TABLE OF AUTHORITIES—Continued

Page

STATUTE:

35 U.S.C. § 112 6

IN THE

Supreme Court of the United States

No. 04-607

LABORATORY CORPORATION OF AMERICA HOLDINGS (doing business as LabCorp),

Petitioner,

v.

METABOLITE LABORATORIES, INC. and COMPETITIVE TECHNOLOGIES, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONER

Respondents' opposition is most notable for what it concedes. Respondents do not dispute that the Federal Circuit construed a patent to confer a legally-protected monopoly barring any doctor in the Nation from even *thinking* about a well-known scientific correlation when looking at a test result. They do not dispute that the Federal Circuit construed a patent claim to include both what is expressly claimed and the exact opposite of what is claimed. They do not dispute that the Federal Circuit failed to apply the induced infringement standard of *Manville Sales Corp.* v. *Paramount Sys., Inc.*, 917 F.2d 544 (Fed. Cir. 1990), in reviewing the evidence. And, as they must, respondents agree that the sum

total of the evidence that the court found sufficient to impose liability on LabCorp for induced infringement was publication of a basic scientific fact. Opp. 2-3.

Respondents accordingly fail to grapple with, much less explain away, the danger the medical community faces if this decision is permitted to stand unreviewed. The Federal Circuit has construed a patent to grant a monopoly over a scientific fact, holding that doctors directly infringe the patent by thinking about a basic medical fact critical for treatment decisions, and that a third party induces infringement merely by reminding doctors of this fact. This decision—if allowed to stand—poses a severe threat to patient care. The opposition fails to dispel the intolerable uncertainty the Federal Circuit has imposed on all those who seek to provide doctors with the medical facts necessary for effective treatment of their patients, and all those who seek to comply with what should be uniform legal standards under the Patent Act. The Court should grant certiorari to resolve this uncertainty.

1. Instead of arguing that the record contains sufficient evidence to impose liability under the proper standard for inducement to infringe, respondents resort to arguing that LabCorp has not preserved its argument on that standard. Opp. 4. That is not so. Whether LabCorp can be held liable for induced infringement under the correct legal standard has been a centrally-contested issue throughout this case. LabCorp argued consistently before the District Court and the Federal Circuit that it could not be liable for inducement because it did not knowingly intend doctors to infringe the '658 patent—the standard articulated by the Federal Circuit in *Manville Sales*. *See* LabCorp Fed. Cir. Br. 35-36.[1] In addition to explicitly referencing the *Manville Sales* standard, LabCorp consistently reinforced its argument that liability

[1] LabCorp stated consistently that it intended single homocysteine tests be used to screen for risk of heart disease, not to aid in a vitamin-deficiency diagnosis. *Id.* at 35.

was improper through citations to other cases in which *Manville Sales* was applied, including *Minnesota Mining & Manufacturing Co.* v. *Chemque, Inc.*, 303 F.3d 1294, 1305 (Fed. Cir. 2002), and *Warner-Lambert Co.* v. *Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003). *See* LabCorp Fed. Cir. Br. 27, LabCorp Fed. Cir. Reply Br. 16; *see also* LabCorp Pet. for Reh'g 1 (stating that the panel decision was contrary to *Warner-Lambert* and *Minnesota Mining*).[2]

Respondents do not contest that the Federal Circuit failed to apply the *Manville Sales* standard here. Instead they claim that the District Court's *jury instruction*, which hewed to the *Manville Sales* standard, was not appealed and is therefore not reviewable. Opp. 5-6. That is a classic red herring. LabCorp's petition is not premised on the trial court's jury instruction, because LabCorp *agrees* that the jury was properly instructed on this point. The petition seeks review of the *Federal Circuit*'s failure to adopt or apply *Manville Sales* in reviewing the sufficiency of the evidence. The Federal Circuit instead applied an alternate, lesser standard for induced infringement—the *Hewlett-Packard* standard—to uphold a finding of liability against LabCorp. And as explained in the petition, if the Federal Circuit had examined the evidence under the *Manville Sales* standard, it should have reversed the District Court's judgment because the sole evidence relied on by the Federal Circuit—LabCorp's dissemination of a basic medical fact—is indisputably insufficient to establish inducement liability under that stand-

[2] Respondents note that LabCorp cited both *Manville Sales* and *Hewlett-Packard Co.* v. *Bausch & Lomb Inc.*, 909 F.2d 1464 (Fed. Cir. 1990), in its Federal Circuit briefing. Opp. 4. Given that the Federal Circuit has announced two divergent standards, however, LabCorp was well-advised to have cited both. Indeed, as explained in the petition, this Court's intervention is needed precisely because the Federal Circuit has adopted two inconsistent standards, each of which purports to be controlling on parties before that court and those who seek to obey the patent laws.

ard. Pet. 16-19. *Nowhere* in the opposition do respondents explain how that evidence can satisfy *Manville Sales*.[3]

There can only be one standard for determining whether the intent requirement of inducement to infringe is satisfied. Yet the Federal Circuit has embraced two such tests over the years, fostering well-recognized and untenable confusion in the law.[4] Respondents nonetheless opine that the Federal Circuit should be capable of "resolving any conflict that may exist in its precedents." Opp. 4. But as LabCorp explained in the petition, this conflict has existed for nearly fifteen years, with no movement within that court to resolve it. And the Federal Circuit, of course, is unique among circuit courts because its patent precedents will not be tested or influenced by the decisions of any other federal court of appeals. The Federal Circuit has demonstrated its inability to resolve the conflict between the *Hewlett-Packard* and *Manville Sales*

---

[3] As noted in the petition, LabCorp was held to have induced infringement of the '658 patent based on its publication of a medical fact, despite having never provided any guidance, instruction, direction, or encouragement to doctors on how to infringe the patent, and even though LabCorp *and* the patent "inventor" understood that doctors order a single homocysteine test to screen for risk of heart disease, not to aid in the diagnosis of vitamin deficiency. *See* Pet. 5-6.

[4] Respondents incorrectly argue that *Hewlett-Packard* "deals with ordinary infringement by inducement" and *Manville Sales* deals with a corporate officer inducing infringement. Opp. 3-4. Each case purports to establish the general standard for induced-infringement liability, and the Federal Circuit has applied *Manville Sales* in cases involving "ordinary infringement by inducement." *See, e.g., Minnesota Mining*, 303 F.3d at 1305; *Mentor H/S, Inc.* v. *Medical Device Alliance, Inc.*, 244 F.3d 1365, 1379 (Fed. Cir. 2001). Indeed, the Federal Circuit *itself* has acknowledged that *Hewlett-Packard* and *Manville Sales* state conflicting liability standards. *See Insituform Tech. Inc.* v. *CAT Contracting, Inc.*, 385 F.3d 1360, 1378 (Fed. Cir. 2004); Pet. 13.

standards, and this case squarely presents the situation where the outcome differs depending on the standard by which the evidence is judged.[5]

2. The Federal Circuit's ruling warrants review for an independent reason: the majority's decision—which held that the term "elevated" in Claim 13 also could be construed to include an opposite "unelevated" state—contravenes this Court's long-held recognition that the public must be able to rely on the express claims of a patent. *See General Elec. Co.* v. *Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938); Pet. 20-22.

Respondents say nothing about the opinion's jarring claim-construction ruling other than to incorrectly assert that LabCorp has offered varying interpretations of the claim term "correlating." Opp. 7-8. LabCorp has consistently argued at each stage of this case that the word "correlating"—whatever it means—expressly applies only to "elevated" results. Claim 13 of the patent provides that when a test indicates an *elevated* level of homocysteine, it should be correlated with a vitamin deficiency. Although the patent provides no guidance as to what "correlating" means, it explicitly limits the circumstances under which one should "correlate" to those where there is an *elevated* level of homocysteine. The

---

[5] Respondents incorrectly assert that LabCorp did not appeal the jury's willfulness determination. Opp. 6-7. LabCorp expressly raised that argument below. *See, e.g.*, LabCorp Fed. Cir. Br. 54 ("Because, for the reasons set forth above, the judgment of infringement cannot stand, the findings of willfulness and enhanced damages should also be reversed. Those findings should also be reversed and vacated for independent reasons."). LabCorp raised the same arguments against both the willfulness finding and the enhanced damages award, *id.* at 54-58, and the Federal Circuit considered all those arguments in the latter context. Pet. 24a. In any event, the principal challenges here are to the holdings on induced infringement and invalidity; if either of those holdings is reversed, the finding of willful infringement necessarily falls as well.

patent simply does not cover correlation of *unelevated* results. *See* Pet. App. 30a-33a (Schall, J., dissenting).

Respondents understandably fail to justify a construction of Claim 13 that includes within its scope both elevated *and* unelevated levels. Nor do they explain how physicians can practice the claim—that is, how physicians can "correlate"—where test results indicate an unelevated homocysteine level. On this point, and as the panel's dissenting judge observed, Claim 13 is simple and direct: without an elevated level, there is no correlating to be done.[6]

3. The opposition does not respond to LabCorp's argument that this patent, which merely teaches a scientific fact rather than describe an actual invention making use of that fact, is indefinite, insufficiently described, and non-enabling as a matter of law. A claim that simply directs a practitioner to "correlate" a test result with a medical condition—without any definition of what "correlate" means beyond the vague, judicially-created meaning "think about the basic scientific association between"—fails all the requirements of patent validity. *See* 35 U.S.C. § 112 ¶¶ 1, 2. It also fails this Court's long-held standard that a method patent cannot just state a scientific fact but must teach the public to *do something* specific with that fact. *See, e.g.*, *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); Pet. 23-26. The invalidity argument is thus deeply intertwined with the other arguments presented in the petition and should be considered together with them.

4. Respondents fail to discount the general applicability of the Federal Circuit's decision or the consequences of allowing it to stand. Opp. 9. To the contrary, they do not deny that the Federal Circuit has upheld a patent purporting to cover a doctor's thought processes. Such a patent construction

[6] As respondents do not contest, the claim limitation at issue here was specifically added to overcome the prior art. Pet. 4, 20.

provides a legally-protected monopoly over a basic scientific fact in a way that prevents a doctor from using his or her medical knowledge without fear of infringement. Pet. 26-27. While respondents assert that they have not yet decided to sue doctors, Opp. 9, they stop short of asserting that the doctors are not infringing the patent. That is because, under respondents' theory and the Federal Circuit's holding, doctors commit direct infringement every time they order an unlicensed homocysteine test and merely *think* about the scientific connection between homocysteine level and vitamin deficiencies. It is immaterial that the patent also requires that a test be done. *Id.* For the patent specifies no particular testing method and the Federal Circuit held that the critical act of infringement occurs whenever a doctor "correlates" the result of a test in his or her mind by thinking that the result may (or may not) signify something about a vitamin deficiency.

Testing methods are patentable; medical facts are not. The sole basis on which respondents distinguish LabCorp from the author of a medical textbook—who would equally be liable for infringement of this patent under the Federal Circuit's ruling—is that LabCorp used to perform single homocysteine tests. This distinction is irrelevant to the Federal Circuit's legal analysis in this case. The court did not distinguish third parties that run tests from third parties that do not; it held LabCorp liable because it was a third party that published to doctors a medical fact that allegedly induced them to order unlicensed tests. If LabCorp is liable here for inducing doctors to infringe, then so too is anyone else who similarly informs doctors that a homocysteine test result might say something about vitamin levels.

For all these reasons, the Court should grant certiorari. But moreover, patent disputes—particularly those with broad national import like this one—are also especially appropriate for inviting the Solicitor General to express the United States' view, given that one panel of Federal Circuit judges can issue a decision governing every lower federal court in

the country. LabCorp accordingly suggests that the Court may wish to invite the Solicitor General to express the views of the United States in this case, as the Court recently has done in other cases presenting similar potential for national impact. Such an invitation is often properly extended when the case on petition involves patent law.[7]

CONCLUSION

For the foregoing reasons, and those in the petition, the petition for a writ of certiorari should be granted and the judgment below reversed.

Respectfully submitted,

JOHN P. HIGGINS
ALSTON & BIRD, LLP
Bank of America Plaza
101 South Tryon Street
Suite 4000
Charlotte, NC 28280
(704) 444-1000

JONATHAN S. FRANKLIN*
CATHERINE E. STETSON
JESSICA L. ELLSWORTH
HOGAN & HARTSON L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5766

* Counsel of Record

Counsel for Petitioner

---

[7] *See, e.g.*, *Honeywell Int'l, Inc.* v. *Hamilton Sundstrand Corp.*, 125 S. Ct. 458 (2004); *McFarling* v. *Monsanto Co.*, 125 S. Ct. 348 (2004); *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 125 S. Ct. 237 (2004); *Duke Univ.* v. *Madey*, 538 U.S. 959 (2003); *Monsanto Co.* v. *Bayer CropScience S.A.*, 537 U.S. 1027 (2002); *Micrel, Inc.* v. *Linear Tech. Corp.*, 537 U.S. 946 (2002).